REMARKS

The claims are 55-88, with claims 55 and 75 being independent. Claims 1-54 have been canceled from this application without prejudice or disclaimer.

Claims 55-88 were presented in an Amendment After Final mailed August 13, 2003. As of the mailing date of this paper, no response to the Amendment After Final has been received, accordingly, claims 55-88 are herein re-presented for examination.

Applicants note that the claim identified as claim 12 in the amendment mailed December 6, 2002 was actually claim 10, which had been cancelled. To avoid any confusion, Applicants have cancelled all previous claims, without prejudice or disclaimer and have presented new claims 55-88. Claims 55 and 56 are re-presented claims 10 and 12 (previously identified as claims 12 and 14), respectively. Claims 23, 27, 28, 30-43, 46, 47, 49-54 are re-presented herein as claims 57, 61, 62, 64-77 and 80-81, 83-88. Where appropriate, the term "Compound (I)", as present in previous claims 12, 14 and 23-54, has been replaced in claims 55-88 with the chemical name of Compound (I), specifically, 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, as defined on page 1, 2nd paragraph of the specification. Support for the added subject matter of claims 55 and 75 may be found in the specification at page 5, lines 1-5. Support for claims 58-60, 63, 78-79 and 82 may be found in the specification at page 5, lines 6-8. No new matter has been added

Applicants wish to notify the Examiner that a divisional of the subject application has been filed with claims directed to a method of treatment of Type II diabetes. comprising administering 2 to 8 mg of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy] benzyl]thiazolidine-2,4-dione of per day. The divisional application was filed on March 21, 2003 and has been assigned U.S. Patent Application No 10/394,858.

Although no official action has been taken regarding new claims 55-88, these claims define the same or similar subject matter and contain many of the same terms as original claims 12, 14 and 23-54 that were examined and were the subject of the Office Action dated March 18, 2003. To expedite prosecution of the subject application, Applicants will address the objections raised in the Office Action to the extent that they pertain to the new claims.

The Examiner had rejected claims 12, 14 and 23-54 under 35 U.S.C. §102(e) as anticipated by Antoncucci and under 35 U.S.C. §103(a) as unpatentable over Antoncucci, in view of Remington's Pharmaceutical Sciences and The Physician's Desk Reference. Applicants respectfully traverse each of these rejections.

The Examiner has maintained the objection made in paper number 6 under 35 U.S.C. §102(e) over Antonucci et al, U.S. Patent No. 5,972,944. Applicants respectfully note that the objection in paper number 6 was directed to claims 9-14, some of which were no longer pending in the subject application. Applicants respectfully request clarification of the rejection but will address the Examiner's objection to the extent that it applies to pending claims 55-88.

In column 18, lines 58 to 62, Antonucci defines the term "preparation" as used in the specification to include formulations in which the active ingredient (with one or more carriers) is surrounded by a capsule (a small soluble container). Methods for producing pharmaceutical capsules are well known in the art and Applicants respectfully submit that Antonucci is merely describing that one way of delivering thiazolidinedione derivatives to treat anovulation, hyperandrogenisation and hirsutism is to provide a unit dose of the active ingredient in a capsule.

The Examiner interprets Antonucci to describe a composition that may be prepared by a two step formulation process comprising:

a) forming a first formulation of the active compound in a carrier, and

b) surrounding the first formulation by a carrier.

Contrary to the Examiner's assertion, the process of the present invention is not the two step process of Antonucci.

According to claims 55 and 75, the first step of the process of this invention comprises preparing a first composition comprising 5 to 20% by weight of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione in a pharmaceutically acceptable form and a pharmaceutically acceptable carrier.

The second step of the process comprises admixing the first composition with at least one pharmaceutically acceptable carrier.

The third step of the process comprises formulating the composition produced in the second step into a pharmaceutical unit dose composition comprising 2 to 8 mg or 1 to

8 mg of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione in a pharmaceutically acceptable form.

As described throughout the specification and specifically in Examples 1 and 2 (see pages 9-10), the first composition prepared in the process of the present invention is a concentrate (see page 4, line 26-30), that is, a dilutable composition (see page 5, lines 1-5) that contains a concentration of Compound (I), in a pharmaceutically acceptable form, that is greater than that present in an administerable composition (page 3, lines 17-20, third paragraph). In Example 1, the first composition (the concentrate) was prepared by wet granulation. This concentrate may be subsequently admixed (diluted) with one or more additional pharmaceutically acceptable carriers in a second processing step to provide compositions that contain an administerable concentration of Compound (I). Advantageously, in the second step of this invention, selected amounts of a single preparation (batch) of the concentrate may be separately diluted, each in a single dilution step, with different amounts of carrier to provide separate diluted compositions that contain different specific concentrations of Compound (I), in a pharmaceutically acceptable form. As described in Example 2, different amounts (specifically, 10, 20, 40 or 80 mg) of the granular concentrate of Example 1 were each separately blended with different amounts of additional carrier to form a set of diluted compositions. These second, diluted compositions may be processed into the pharmaceutical unit dose compositions (e.g., tablets) that contain 1 to 8 mg (specifically, 1, 2, 4 or 8 mg) of Compound (I) in a pharmaceutically acceptable form.

Contrary to the Examiner's interpretation, in the present invention, the second composition is not the administerable dosage form - the administerable form (the pharmaceutical unit dose composition) is prepared from the second composition.

Accordingly, Applicants respectfully submit that Antonucci fails to describe or suggest the process of the subject invention. Antonucci also fails to describe or suggest the particular unit dosage concentration of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (2 mg to 8 mg unit dose or 1 mg to 8 mg unit dose) of the present invention. In addition, Antonucci fails to describe or suggest the preparation or use of a first composition containing from 5-20 wt% of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione in pharmaceutically acceptable form.

Accordingly, Applicants respectfully submit that Antonucci fails to describe each and every element of the present claims, and therefore does not anticipate the present claimed invention.

The Examiner also rejected claims 12, 14 and 23-54 as allegedly unpatentable over Antonucci, in view of Remington's Pharmaceutical Sciences and The Physician's Desk Reference (PDR). Applicants respectfully traverse this rejection.

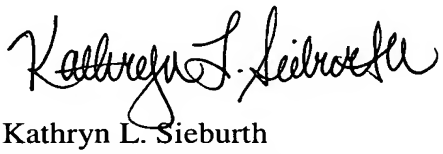
As an initial matter, Applicants respectfully wish to point out that the PDR document is not prior art in this case and thus cannot be used to support an obviousness rejection. The filing date of the international patent application, upon which the subject application is based, is June 2, 1998, which claims priority to foreign applications filed on June 5, 1997 and June 18, 1997. The PDR document, published in 2000, is allegedly based on product labeling information dated June 15, 1999. The filing date of the parent international patent application pre-dates both the publication date of the PDR and the product label information date by more than a year. Accordingly, Applicants respectfully submit that the rejection under 35 U.S.C. §103(a), to the extent that it is based on the PDR document, is moot.

To support the rejection under 35 U.S.C.§ 103(a), the Examiner has essentially repeated the interpretation of Antonucci that was used to support the rejection under 35 U.S.C. §102(e). As Applicants have described above, the present invention is directed to a technique that is neither described nor suggested by Antonucci. Applicants respectfully submit that there is nothing in the newly cited Remington's Pharmaceutical Sciences document that cures the deficiencies of Antonucci. Accordingly, Applicants respectfully submit that the present invention is patentable over the disclosures of Antonucci and Remington's, whether considered alone or in combination.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the subject application is in condition for allowance. Should the Examiner believe that issues remain outstanding, she is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

This Amendment is being filed together with Petition for Extension of Time and a Request for Continued Examination. In the event that these papers get separated, this constitutes a Petition for Extension of Time for the minimum period required to effect timely filing of this Amendment, together with an authorization to charge any fees under 37 C.F.R. §1.16 or §1.17 which may be required by these papers to Deposit Account No. 19-2570.

Respectfully submitted,



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